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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,730	04/24/2001	Se-Jin Lee	JHU1470-3	6537

7590

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/841,730

Applicant(s)

LEE ET AL.

Examiner

Joseph Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This application filed April 24, 2001, is a continuation in part of 09/626,896, filed July 7, 2000, which is a continuation in part of 09/485,046, filed May 5, 2000, which a national stage filing of PCT/US98/15598, filed July 28, 1998, which claims benefit to US provisional application 60/054,461, filed August 1, 1997.

Claims 1-42 are pending and currently under examination.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 13, 14, 20 and 40-42, drawn to a transgenic non-human mammal comprising a transgene encoding a truncated Activin Type II receptor, classified in class 800, subclass 14.
- II. Claims 1-5, 13, 14, 20 and 40-42, drawn to a transgenic bird comprising a transgene encoding a truncated Activin Type II receptor, classified in class 800, subclass 19.
- III. Claims 1-5, 13, 14, 20 and 40-42, drawn to a transgenic fish comprising a transgene encoding a truncated Activin Type II receptor, classified in class 800, subclass 20.

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- IV. Claims 6-10, 15, 16, 20 and 40, drawn to a transgenic non-human mammal comprising a transgene encoding a myostatin prodomain, classified in class 800, subclass 14.
- V. Claims 6-10, 15, 16, 20 and 40, drawn to a transgenic bird comprising a transgene encoding a myostatin prodomain, classified in class 800, subclass 19.
- VI. Claims 6-10, 15, 16, 20 and 40, drawn to a transgenic fish comprising a transgene encoding a myostatin prodomain, classified in class 800, subclass 20.
- VII. Claims 11, 12, 17-20, 24-39 and 40, drawn to a transgenic non-human mammal comprising a transgene for a follistatin gene, classified in class 800, subclass 14.
- VIII. Claims 11, 12, 17-20, 24-39 and 40, drawn to a transgenic bird comprising a transgene for a follistatin gene, classified in class 800, subclass 19.
- XI. Claims 11, 12, 17-20, 24-39 and 40, drawn to a transgenic fish comprising a transgene for a follistatin gene, classified in class 800, subclass 20.
- X. Claims 21-24, drawn to a method of inhibiting myostatin binding to Activin type II receptor comprising providing follistatin, classified in class 530, subclass 350.

Claims 1-5, 13, 14, 41 and 42 are generic to groups I-III and will be examined to the extent they encompass the elected invention. Claims 11, 12, 17-19 and 24-39 are generic to groups VII-IX and will be examined to the extent they encompass the elected invention. Claims 6-10, 15 and 16 are generic to groups VII-IX and will be examined to the extent they encompass

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the elected invention. Claims 20 and 40 are generic to groups I-IX and will be examined to the extent they encompass the elected invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are distinct inventions. In the instant case, each of the groups are drawn to different and distinct types of transgenic animals which are not obvious one over the other. Further, the methodology required to make each of these various transgenic animals is different requiring different search and consideration for each of the groups.

Inventions IV-VI are distinct inventions. In the instant case, each of the groups are drawn to different and distinct types of transgenic animals which are not obvious one over the other. Further, the methodology required to make each of these various transgenic animals is different requiring different search and consideration for each of the groups.

Inventions VII-IX are distinct inventions. In the instant case, each of the groups are drawn to different and distinct types of transgenic animals which are not obvious one over the other. Further, the methodology required to make each of these various transgenic animals is different requiring different search and consideration for each of the groups.

Inventions I-III, IV-VI and VII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn the use and presence of different transgenes in each of the animals. The specific transgenes are materially different one from the other requiring

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a different search and consideration for each of the specific sequences, and consequently each of the animals containing said transgenes.

Inventions I-IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of group X do not use or require the products of groups I-IX. Further, groups I-IX use polynucleotide in animals where the method of group X requires the use of a protein, follistatin, to inhibit the binding between through the binding of myostatin.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Deborah Crouch

Joseph T. Woitach

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630